

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: All Direct Purchaser Actions	Case No. 1:15-cv-07488-CM-RWL
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**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION IN
LIMINE NO. 6: PRECLUDE "LITIGATION RISK" OR "RISK
AVERSION" OR PURPORTED "EARLY ENTRY" AS
PROCOMPETITIVE JUSTIFICATIONS**

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I. INTRODUCTION

The Court should preclude Forest from arguing or adducing evidence that its reverse payments to Mylan were purportedly justified because Forest was allegedly risk averse in connection with the ‘703 patent infringement lawsuit. The Court should likewise bar the fallacious argument that the reverse payment is justified because it allowed “earlier” generic entry, *i.e.*, entry before expiration of the ‘703 patent. Both arguments are impermissible defenses under antitrust law generally and *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

II. ARGUMENT

A. The Court Should Bar Risk Aversion and/or Litigation Risk as a Procompetitive Justification

Under the rule of reason and *Actavis* specifically, risk aversion is not a cognizable defense. The rule of reason “focuses directly on the challenged restraint’s impact on competitive conditions.” *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 688 (1978); *see also FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 459 (1986) (justifications are not cognizable “[a]bsent some countervailing procompetitive virtue”); Am. Bar. Ass’n, *Model Jury Instructions in Civil Antitrust Cases* (2016 ed.), Instruction 3C at Notes (“Benefits that are unrelated to competition should be irrelevant to the analysis.”). Whether any party was risk averse does not bear on the question whether the reverse payments enhanced competition under the rule of reason.

In *Actavis* specifically, the Supreme Court explained that risk aversion was not a cognizable justification for a reverse payment. The Supreme Court explained that a reverse payment agreement raises anticompetitive concerns precisely *because* it assures competition-free sales by averting the risk of competition. *E.g.*, *Actavis*, 570 U.S. at 156 (“[A] reverse payment . . . [raises] concern that a patentee is using its monopoly profits to avoid the *risk* of patent

invalidation or a finding of noninfringement.”) (emphasis added). Accordingly, the Supreme Court rejected any defense argument that risk aversion can explain or justify a reverse payment:

The owner of a particularly valuable patent might contend, of course, that even a small *risk of invalidity justifies a large payment*. But, *be that as it may*, the payment (if otherwise unexplained) likely seeks to prevent the *risk of competition*. And, as we have said, *that consequence constitutes the relevant anticompetitive harm*.

Id. at 157 (emphasis added). It would be nonsensical for the “relevant anticompetitive harm” to also be a procompetitive justification, and court after court has so held. *See King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 403-09 (3d Cir. 2015) (repeatedly emphasizing that reverse payments are anticompetitive because they prevent “the risk of competition”); *In re Lidoderm Antitrust Litig.*, No. 3:14-md-02521-WHO, 2018 WL 7814761, at *7 (N.D. Cal. Feb. 7, 2018) (granting motion *in limine* that “Defendants may not argue that the Settlement in and of itself was procompetitive by removing litigation uncertainty *for defendants*. Defendants’ justifications (providing certainty and fewer distractions) implicate at-issue waiver and may, at most, be relevant to whether the reverse payments were ‘large and unexplained,’ but cannot be argued as procompetitive”) (emphasis in original); *Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-CV-2768, 2017 WL 2362400, at *5 (E.D. Pa. May 31, 2017) (granting motion *in limine*: “To the extent that Defendants nonetheless intend to introduce evidence regarding Cephalon’s litigation uncertainty, such evidence is inadmissible.”); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, No. 2:06-CV-1797, 2015 WL 5783603, at *8 (E.D. Pa. Oct. 5, 2015) (excluding expert opinion in reverse payment case that “reverse payments were made to avoid litigation uncertainty” because the risk of the brand losing infringement litigation is not relevant under *Actavis*). *See also* Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, and Carl Shapiro, *Activating Actavis*, ABA ANTITRUST, Fall 2013, at 20 (“The [Supreme] Court says that payments

to avoid even a small risk of competition are antitrust violations. That is reason enough to deny a risk-aversion defense.”) (footnote omitted).

Any argument that “risk aversion” is a cognizable defense for a reverse payment merely parrots *Actavis*’s dissent. *Actavis*, 570 U.S. at 171-72 (Roberts, C.J., dissenting).

Defendants may cite *In re Wellbutrin XL Antitrust Litigation*, 868 F.3d 132, 167-68 (3d Cir. 2017), but that decision is off-point and did not (and could not) change controlling Supreme Court law. In *Wellbutrin XL*, the focus was not on justifications for the reverse payment, but on whether the reverse payment was itself sufficient evidence of patent invalidity to overcome a causation defense. A “blocking” patent held by a third party (not the brand’s own patent) was the identified superseding cause of harm. The plaintiffs had not adduced any evidence the blocking patent was invalid or noninfringed. The court held that the reverse payment standing alone was insufficient evidence of invalidity or noninfringement of a patent that was not the brand’s own. In that context, the court reasoned that the reverse payment did not show that the patent was weak because it may have merely reflected the brand’s fear that the generic could launch at risk of infringing the third party blocking patent, which the brand company did not hold, and thus had no standing to assert. *Id.* at 167-68. The court’s rationale was limited to whether a reverse payment alone could serve as evidence of causation sufficient to overcome evidence of the validity and infringement of a patent that the brand did not hold.

The Court should likewise block any attempt by Defendants to “backdoor” a risk aversion defense under the guise of the avoidance of “business (un)certainty.” Whether stated as “litigation uncertainty” or “business uncertainty,” Defendants are seeking to justify their reverse payments as eliminating risk, the very harm that *Actavis* identified as anticompetitive.

The primary question is whether defendants’ actions “diminish overall competition, and hence consumer welfare.” *K.M.B. Warehouse Distrib., Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 128 (2d Cir. 1995). *See also Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308–09 (3d Cir. 2007) (“The primary goal of antitrust law is to maximize consumer welfare by promoting competition among firms.”). Accordingly, the antitrust laws were enacted for “the protection of competition, not competitors.” *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962); *see also Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (same). Thus, the rule of reason analysis focuses on whether defendants’ conduct “had an *actual* adverse effect on competition as a whole in the relevant market” not on any one competitor. *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 197 (S.D.N.Y. 2018) (quoting *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F. 3d 98, 104 (2d Cir. 2010) (second emphasis added).

The sort of business rationales asserted here (*see, e.g.*, Declaration of Dan Litvin, Ex. 26 ¶¶68-69, 72, 75 (Expert Report of Lona Fowdur, Ph.D.) – which yield benefits to the parties but do not promote competition overall – are not legally cognizable defenses to otherwise anticompetitive conduct. As the Supreme Court has held, “[t]he promotion of self-interest alone does not invoke the rule of reason to immunize otherwise illegal conduct. It is only if the conduct is not unlawful in its impact in the marketplace or if the self-interest coincides with the statutory concern with the preservation and promotion of competition that protection is achieved.” *United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 375 (1967), *overruled on other grounds by Cont’l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977)). *See also United States v. Masonite Corp.*, 316 U.S. 265, 276 (1942) (“the fact that there were business reasons which made the arrangements desirable” was not a justification for a patent settlement that fixed prices). Or, as the court in *Lidoderm* stated, “justifications that benefit only the settling parties and not the

market or consumers” are not admissible. *Lidoderm*, 2018 WL 7814761, at *2. *See also id.* at *6 (proffered justifications “that benefit only the settling parties (and not the market or consumers) are not” considered under Rule of Reason). *See also Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1341 (Fed. Cir. 2006) (explaining that the Supreme Court has rejected the argument that anticompetitive conduct “should be excused on the ground that it provided benefits and furthered a public policy unrelated to competition”); *LePage’s, Inc. v. 3M*, 324 F.3d 141, 163 (3d Cir. 2003) (defense that defendant was merely “act[ing] in furtherance of its economic interests does not constitute the type of business justification that is an acceptable defense to §2 monopolization”); *Freeman v. San Diego Ass’n of Realtors*, 322 F.3d 1133, 1152 n.24 (9th Cir. 2003) (“It does not matter that Fallbrook and Valley Center would have operated at a loss in a competitive environment. Their precarious financial situation may have explained their intransigence, but it does not transform it into a viable defense. If there is any argument the Sherman Act indisputably forecloses, it is that price fixing is necessary to save companies from losses they would suffer in a competitive market.”); *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1184 (N.D. Cal. 2017) (“While maintaining good business relations with Endo might have been a key goal of Teikoku, Teikoku does not show how that goal has any pro-competitive impact on consumers or on the industry in general, or on any other consideration relevant to a rule of reason analysis. That justification, if true, does nothing to negate the inference (or according to plaintiffs, the actuality) that the payments agreed to by Endo and Teikoku were to delay competition.”) (emphasis in original); *Meijer Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38, 63 n.24 (D.D.C. 2008) (“[a]lthough the Court does not reach the merits of Barr’s proffered procompetitive benefits, the Court notes that ‘benefits’ are only procompetitive when they promote and protect competition, not competitors

... and when they do not rely on the assumption that competition itself is unreasonable”) (citations omitted); Litvin Decl. Ex. 27, Am. Bar Ass’n, *Antitrust Law Developments (Eighth)* at 75 (8th ed. 2017) (“Because the rule of reason focuses on anticompetitive effects, factors unrelated to the restraint’s effect on competition are generally irrelevant to the analysis.”).

Accordingly, any argument by Forest that it had a “business reason” or that it made “business sense” to settle is not a cognizable pro-competitive justification, and the jury should not hear that evidence or argument. *See Lidoderm*, 2018 WL 7814761, at *7 (“Risk aversion is not admissible as to either the step one ‘unexplained’ *Actavis* factor or on step two as a procompetitive justification (because it is a party-specific justification.)”).

B. The Court Should Bar Purported “Early Entry” as a Procompetitive Justification

Forest should also be precluded from asserting that Mylan’s July 11, 2015 entry was “early” and therefore a procompetitive justification for the reverse payment. *See, e.g.*, Litvin Decl. Ex. 26, Expert Report of Lona Fowdur, at ¶74. The fact that a reverse payment settlement permits entry before expiration of the patent in litigation is not a procompetitive justification for the payment, and what Forest has to justify as procompetitive is the *payment*. *See Actavis*, 570 U.S. at 158 (“[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; *one who makes such a payment may be unable to explain and to justify it.*”) (emphasis added). *See also Nat’l Collegiate Athletic Ass’n v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85, 104 (1984) (defendant must show “the challenged restraint enhances competition.”); *In re Impax Labs.*, -- F.T.C. --, No. 9373, 2019 FTC LEXIS 25, at *97 (F.T.C. 2019) (“to justify a challenged restraint, [an antitrust defendant] must articulate the specific link between the challenged restraint and the purported justification, and demonstrate that the restraint in fact advance[s] procompetitive goals.”) (internal quotes omitted).

Actavis itself involved a settlement that permitted entry 65 months before expiration of the brand manufacturer's patent as opposed to the three months here. *Actavis*, 570 U.S. at 145. The Supreme Court took "this fact as evidence that the agreement's anticompetitive effects fell within the scope of the exclusionary potential of the patent." *Id.* at 147 (internal quotes omitted). However, it did "not agree that that fact, or characterization, can immunize the agreement from antitrust attack." *Id.*

Evidence that the reverse payment settlement did not require even later generic entry is no justification for the delay in competition that the payment did cause. Indeed, such a proffered justification takes as an assumption that the generic could have been justifiably taken a payment to delay launching until patent expiry because it fell within what Forest believed were the claims of its patent. This notion, however, merely restates the so-called "scope of the patent" standard that *Actavis* rejected.

Nor does such an attempted justification explain why the reverse payment is not a payment for delay. Indeed, the ultimate jury question is whether the reverse payment resulted in entry later than otherwise would have occurred without the payment, notwithstanding that entry occurred prior to patent expiry. And any argument that Forest's payment to Mylan somehow *sped up* Mylan's generic entry is nonsensical. See *FTC v. Actavis, Inc. (In re Androgel Antitrust Litig. (No. II))*, MDL No. 2084, 2018 WL 2984873, at *17 (N.D. Ga. June 14, 2018) ("It would make no sense for [the brand] to pay the Generics tens of millions of dollars if it could get the Generics to enter on the same date without paying them all of that money. Nor would it make sense for the Generics to agree to delay entry for free if they could receive tens of millions of dollars to do the same thing."); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751-52 (E.D. Pa. 2014) ("a reverse payment of cash by the brand-name manufacturer to the potential generic

manufacturer is likely to induce the generic to agree to enter the market at a date later than that to which it would otherwise agree based solely on the estimated strength of its litigation position.”).

III. CONCLUSION

For the reasons set forth above, Plaintiff’s motion should be granted.

Dated: May 24, 2019

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CERTIFICATE OF SERVICE

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